



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0014]

BASF Plant Science, LP; Availability of a Draft Plant Pest Risk Assessment and Draft Environmental Assessment for Canola Genetically Engineered for Altered Oil Profile and Resistance to an Imidazolinone Herbicide

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service is making available for public comment a draft plant pest risk assessment (PPRA) and draft environmental assessment (EA) for canola designated as event LBFLFK, which has been genetically engineered (GE) to allow for the synthesis of long chain omega-3 polyunsaturated fatty acids, including eicosapentaenoic acid and docosahexaenoic acid, from oleic acid in canola seed. The GE canola has also been genetically engineered for resistance to an imidazolinone herbicide. We are making the draft PPRA and draft EA available for public review and comment.

DATES: We will consider all comments that we receive on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to

<http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0014>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2018-0014, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0014> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

The petition is also available on the APHIS website at:
http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml under APHIS petition 17-321-01p.

FOR FURTHER INFORMATION CONTACT: Dr. Subray Hegde, Acting Program Director, Biotechnology Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; 301-831-3901; email: Subray.Hegde@usda.gov. To obtain copies of the petition, contact Ms. Cindy Eck at (301) 851-3892; email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products

altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS received a petition (APHIS Petition Number 17-321-01p) from BASF Plant Science, LP, of Florham Park, NJ (BASF), seeking a determination of nonregulated status of canola (*Brassica napus* L.) designated as event LBFLFK, which has been genetically engineered to allow for the synthesis of long chain omega-3 polyunsaturated fatty acids (LC-PUFAs), including eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), from oleic acid in canola seed. The canola has also been genetically engineered for resistance to an imidazolinone herbicide. The BASF petition states that information collected during field trials and laboratory analyses indicates that LBFLFK canola is not likely to be a plant pest and therefore should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process¹ for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice² published in the *Federal Register* on March 30, 2018 (83 FR 13722-13723, Docket No. APHIS-2018-0014), APHIS

¹ On March 6, 2012, APHIS published in the *Federal Register* (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms. To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

² To view the notice, the petition, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0014>.

announced the availability of the BASF petition for public comment. APHIS solicited comments on the petition for 60 days ending on May 29, 2018, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. APHIS received eight comments on the petition. Three of the comments were from individuals, three were from the canola industry, one was from a public interest group, and one was from a State government. APHIS has evaluated the issues raised during the comment period and, where appropriate, has provided a discussion of these issues in our draft environmental assessment (EA).

After public comments are received on a completed petition, APHIS evaluates those comments and then provides a second opportunity for public involvement in our decisionmaking process. According to our public review process (see footnote 1), the second opportunity for public involvement follows one of two approaches, as described below.

If APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises no substantive new issues, APHIS will follow Approach 1 for public involvement. Under Approach 1, APHIS announces in the *Federal Register* the availability of APHIS' preliminary regulatory determination along with its draft EA, preliminary finding of no significant impact (FONSI), and its draft plant pest risk assessment (PPRA) for a 30-day public review period. APHIS will evaluate any information received related to the petition and its supporting documents during the 30-day public review period.

If APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues, APHIS will follow Approach 2.

Under Approach 2, APHIS first solicits written comments from the public on a draft EA and draft PPRA for a 30-day comment period through the publication of a *Federal Register* notice. Then, after reviewing and evaluating the comments on the draft EA and draft PPRA and other information, APHIS will revise the PPRA as necessary and prepare a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a FONSI or a notice of intent to prepare an environmental impact statement). For this petition, we are using Approach 2.

As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS prepares a PPRA to assess the plant pest risk of the article. APHIS also prepares the appropriate environmental documentation—either an EA or an environmental impact statement—in accordance with NEPA, to provide the Agency and the public with a review and analysis of any potential environmental impacts that may result if the petition request is approved.

APHIS has prepared a draft PPRA and has concluded that BASF canola designated as event LBFLFK, which has been genetically engineered to allow for the synthesis of long chain omega-3 polyunsaturated fatty acids, including EPA and DHA, from oleic acid in canola seed, and for resistance to an imidazolinone herbicide, is unlikely to pose a plant pest risk. In section 403 of the Plant Protection Act, "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS has also prepared a draft EA in which we present two alternatives based on our analysis of data submitted by BASF, a review of other scientific data, field tests conducted under APHIS oversight, and comments received on the petition. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of canola designated as event LBFLFK, or (2) make a determination of nonregulated status of canola designated as event LBFLFK.

The draft EA was prepared in accordance with (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) U.S. Department of Agriculture regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

In accordance with our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments on our draft EA and our draft PPRA regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 30 days from the date of this notice. Copies of the draft EA and the draft PPRA, as well as the previously published petition, are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above.

After the 30-day comment period closes, APHIS will review and evaluate any information received during the comment period and any other relevant information. After reviewing and evaluating the comments on the draft EA and the draft PPRA and other information, APHIS will revise the PPRA as necessary and prepare a final EA. Based on the final EA, APHIS will prepare a NEPA decision document (either a FONSI or a notice of intent to

prepare an environmental impact statement). If a FONSI is reached, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will also publish a notice in the *Federal Register* announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 1st day of April 2019_.

Kevin Shea

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019-06630 Filed: 4/3/2019 8:45 am; Publication Date: 4/4/2019]